

PART 34 AMDT**Claims**

1. Transdermal therapeutic system (TTS) comprising a drug-containing adhesive matrix, in which the drug is Rotigotine ((--)-5,6,7,8-tetrahydro-6-[propyl[2-(2-thienyl)ethyl]amino]-1-naphthol), characterized in that the adhesive matrix contains a hot-meltable adhesive, said hot-meltable adhesive consisting of one adhesive or a mixture of different adhesives or of a mixture of an adhesive and a softener and exhibiting at 160°C a dynamic viscosity of not more than 100 Pa.s.
2. TTS as in claim 1, in which the Rotigotine is dispersed or partly or completely dissolved in said hot-meltable adhesive.
3. TTS as in one of the preceding claims, for which said drug-containing adhesive matrix is produced by metering the Rotigotine into the solvent-free melt of the adhesive matrix at a temperature of between 120°C and 160°C.
4. TTS as in one of the preceding claims, in which the hot-meltable adhesive consists of a mixture of an amine-resistant silicone adhesive and at least one suitable softener.
5. TTS as in claim 4, in which the softener is an organic wax.
6. TTS as in claim 4 or 5, in which the softener is ceresine or ozokerite.
7. TTS as in one of the preceding claims, in which the proportion of the Rotigotine in the adhesive layer is 4-40 weight%.
8. TTS as in one of the preceding claims, in which the proportion of the Rotigotine in the adhesive layer is 9-30 weight%.
9. TTS as in one of the claims 1-7, in which the proportion of the Rotigotine in the adhesive layer is 20-40 weight%.
10. TTS as in one of the preceding claims, in which the Rotigotine is present as the active ingredient in form of a base.

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11. TTS as in one of the preceding claims, in which the drug-containing adhesive matrix additionally contains an internal-phase component selected from the group of
 - (a) hydrophilic or amphiphilic polymers
 - (b) hydrophilic or amphiphilic copolymers
 - (c) mixtures of (a) and/or (b) with pharmaceutically acceptable softeners
 - (d) condensates from glycerin and fatty acids or polyols
 - (e) suitable mixtures of the components (a)-(d)
12. TTS as in claim 11, in which the internal-phase component is selected from the group of polysaccharides, substituted polysaccharides, polyethylene oxides, polyvinyl acetates, polyvinyl pyrrolidones, copolymers from polyvinyl pyrrolidone and (poly)vinyl acetate, polyethylene glycol, polypropylene glycol, copolymers from ethylene and vinyl acetate, glycerin-fatty acid esters as well as mixtures of polyvinyl alcohol with glycerin.
13. TTS as in one of the claims 1-3, characterized in that the adhesive matrix comprises
 - (a) 50-99 weight% of said hot-meltable adhesive
 - (b) 4-40 weight% Rotigotine
 - (c) 0-40 weight% of an internal-phase component
 - (d) 0-10 weight% other adjuvants
14. TTS as in one of the claims 1-3 or 7-13, for which said hot-meltable adhesive is selected from among
 - (a1) an EVA adhesive
 - (a2) an SxS adhesive, or
 - (a3) a mixture of
 - (i) 70-99 weight% of an amine-resistant silicone adhesive
 - (ii) 1-30 weight% of a suitable softener

15. TTS for the transdermal administration of Rotigotin, said TTS comprising a Rotigotine-containing layer that is characterized in that it
 - (a) contains Rotigotine in a percentile proportion of at least 20 weight%,
 - (b) has a Rotigotine content of at least 2.0 mg/cm², and
 - (c) optionally contains an organic wax and/or internal-phase component in an amount sufficient to retard the release of the active substance.
16. TTS as in claim 15, characterized in that the Rotigotine is transported through the skin at a steady-state flux rate of 100-500 µg per hour over a period of at least 5 days.
17. TTS as in claim 15 or 16, characterized in that the Rotigotine is transported through the human skin at a flux rate of 100-500 µg per hour over a period of at least 7 days.
18. TTS as in one of the claims 15-17, characterized in that the TTS induces in the patient an average plasma concentration of 0.4 to 2 ng/ml Rotigotine for a period of at least 5 days.
19. Method for producing a TTS that encompasses an adhesive matrix containing Rotigotine as the drug, characterized in that prior to their lamination the components of the adhesive matrix are melted and homogenized, solvent-free, at temperatures of between 70°C and 200°C.
20. Method as in claim 19, characterized in that the components of the adhesive matrix are melted and homogenized in an extruder.
21. Use of Rotigotine in the production of a TTS by the hot-melt method, characterized in that the Rotigotine is introduced, at temperatures between 70°C and 200°C, in the TTS adhesive matrix that has been premelted without solvents.

22. Method or use as in one of the preceding claims, whereby the hot-melting process takes place at temperatures between 120°C and 160°C.
23. Method or use as in one of the preceding claims, whereby the Rotigotine is introduced, in the adhesive matrix melt, in its solid state.
24. Method or use as in one of the preceding claims, whereby the adhesive matrix, produced by the hot-melting process, contains Rotigotine at a purity level of at least 98% as measured by HPLC at 220 nm and 272 nm.
25. TTS, method or use as in one of the preceding claims, in which, in lieu of Rotigotine, a Rotigotine prodrug is used or present.
26. TTS, method or use as in claim 25, in which the Rotigotine prodrug is a Rotigotine ester or carbamate.